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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,534	11/07/2002	Danny L Serna	UCIVN-014US	4897

7590 07/01/2005

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EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,534	SERNA ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *20-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-19, drawn to a first composition comprising: PEG-Hb, electrolyte, soluble protein, nutritional formulation, cardiovascular agent.

Group II, claims 20-23, drawn to a second composition comprising: PEG substituted bovine hemoglobin.

Group III, claims 24-27, drawn to a third composition comprising: an oxygen, nutritional and electrolyte environment.

Group IV, claims 28-30, drawn to a method for harvesting organs comprising perfusing the organ with a composition comprising: a solution which is normokalemic and hypocalcemic and containing bovine PEG-Hb.

An international or national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the of following combinations of categories;

(1) a product and a process specially adapted for the manufacture of said product; or
(2) a product and a process of use of said product; or
(3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) a process and an apparatus specifically designed for carrying out said process; or
(5) a product, a process specially adapted for the manufacture of the said product and an apparatus specifically designed for carrying out said process. 37 CFR 1.475.

The groups of invention do not fall within any category because none of the solutions AS CLAIMED are hypocalcemic and normokalemic which is required by the method claims of Group IV.

PCT Rule 13 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of use and the additional composition and method claims each constitute a separate group.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with R. Buyan on 6/14/05 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The telephone election was necessitated by an error made by the examiner. The restriction mailed 3/30/05, while having applicant's serial number, is clearly not related to applicants' claims. Any inconvenience is regretted.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 371 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Specification

The disclosure is objected to because of the inclusion of new matter into the disclosure of an application which claims to be a 371 filing of an international application.

Applicant is required to cancel the new matter in the reply to this Office Action.

The specification has been entirely rewritten as compared to the originally filed international specification and is replete with new matter.

For example, insertion of
"Na_2HPO_4, NaH_2PO_4 or both",
"comprises carbohydrates and its metabolites",
"at least one soluble protein",
"at least one agent acting on the cardiovascular system",
"an antioxidant" as well as the itemized list of antioxidants found on page 3, lines 20-23.
"agents acting on the cardiovascular systems such as anticoagulants and antiarrythmic agents in buffers"
"a simple sugar"

"0.3M tromethamine solution"
are all completely without support in the originally filed international application.

See MPEP 1893.01(a)(3)[R-2] "The fact that an amendment made to the international application during the international phase was entered in the national stage application does not necessarily mean that the amendment is proper. Specifically, amendments are not permitted to introduce "new matter" into the application. See PCT Article 34(2)(b). Where it is determined that such amendments introduce new matter into the application, then the examiner should proceed as in the case of regular U.S. national applications filed under 35 U.S.C. 111(a) by requiring removal of the new matter and making any necessary rejections to the claims. See MPEP § 608.04 and § 2163.06.".

In fact, the amendments to the specification and drawings proposed under Articles 19 and 34 were REFUSED ENTRY in the international application because of the incorporation of new matter.

In spite of this fact, the instant specification is identical to the proposed amendment which WAS REFUSED ENTRY in the international application because of new matter issues.

Claim Rejections - 35 USC § 112

NEW MATTER

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Insertion of the phrase "at least one agent acting on the cardiovascular system" is considered to be new matter because it has no support in the originally filed international specification and is part of an amendment which was refused entry in the international application because of new matter.

Insertion of the phrase "at least one soluble protein" is without support in the originally filed international application.

Insertion of "a simple sugar" is without support in the originally filed international application.

Insertion of the limitations (Na_2HPO_4/NaH_2PO_4) (Na_2HPO_4, NaH_2PO_4 or both) has no support in the originally filed international specification and is now sprinkled throughout the instant specification. The originally filed disclosure stipulated Na_3PO_4.

Insertion of 0.3M tromethamine solution is with support in the originally filed international specification.

Insertion of the phrase (comprises carbohydrates and its metabolites) has no support in the originally filed international specification. No mention of carbohydrate metabolites is found.

Insertion of "an antioxidant" has no support in the originally filed international specification as well as the itemized list of antioxidants found on page 3, lines 20-23.

Insertion of "agents acting on the cardiovascular systems such as anticoagulants and antiarrythmic agents in buffers" is without support in the originally filed international application.

Please note that in the international application, entry of amendments to the specification, drawings and claims proposed under Articles 19 and 34 were refused because of new matter. These amendments which were refused entry in the international application are now in the instant claims. See PCT IPEA 409 for PCT/US00/16895 which is part of the record.

INDEFINITE

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It cannot be understood if the "one or more physiologically essential electrolyte" contains all the salts listed in claim 2. This is because the construction of the claim is faulty in that it contains " and Na_2HPO_4, NaH_2PO_4 or both" which would lead one to interpret the claim to be fulfilled if the solution contains only one salt such as NaCl.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-7, 12, 16-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nakajima *et al.* [IDS].

The claims are directed to a composition comprising (a) PEG-Hb, (b) electrolyte, (c) soluble protein, (d) nutritional formulation, (e) agent acting on the cardiovascular system.

The references are relied upon as explained below.

Nakajima *et al.* disclose a solution comprising :
(a) PEG-Hb,
(b) Na and Cl ions,
(c) PEG-methemoglobin,
(d) glucose,
(e) HES

HES is considered to fulfill the claim limitation of component (d) because it has osmotic properties and would, therefore, act on the cardiovascular system to prevent unfavorable osmotic effects such as edema.

With regard to claims 16-19, insofar as these compositions rely on the use of a solution which instead of being characterized by technical features suitable for the identification of a solution, is imprecisely defined by means of functional features which merely recite a desired result, the subject matter is considered to be anticipated by the disclosure of the prior art.

Claims 1, 2, 5-10, 12, 16-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 6,582,953 [A].

The claims have discussed above and further comprise components as listed in the rejected claims.

US 6,582,953 disclose in Table 1 a solution comprising:
PEG-Hb up to 20% by volume, electrolytes $MgSO_4$, KCl, $CaCl_2$, NaCl, $NaHCO_3$, NaH_2PO_4, insulin, dextrose, heparin, ascorbic acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,582,953 [A] in view of AU 517547 [N] or Ebihara *et al.* [U] or JP 09-151134 [O].

The claimed composition has been discussed above and further requires human albumin (claims 3, 11) or human insulin (claims 4 or 11) or lidocaine HCL (claims 11, 13) with a pH of 7.1 @37°C (claims 14, 15).

US 6, 582, 953 includes albumin and insulin (Table 1) in the disclosed composition but do not restrict the type or source of the albumin or insulin. The pH of the solution is 7.0-7.6 (col. 8, l. 38).

AU 517547 uses human serum albumin in an organ perfusate.

The use of a human source for the generic albumin used in US '953 would have been obvious because it has been used in organ perfusates as demonstrated in AU 517547.

Ebihara *et al.* disclose that human insulin has slightly more favorable effects than porcine insulin (p. 22).

The use of a human source for the generic insulin used in US '953 would have been obvious when taken with Ebihara *et al.* because one of skill in the art may freely choose any source of insulin. Human insulin is widely available and is considered to be better than porcine insulin when used for humans

JP 09-151134 includes lidocaine in a solution used to perfuse organs.

The inclusion of lidocaine in the perfusate of US '953 when used for cardiac preservation, as in Example 3, would have been obvious when taken with JP 09-151134 which teaches the inclusion of lidocaine in such a solution used for cardiac transplantation.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same

purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

With regard to the concentrations of the components used in the claimed solution and the exact pH of the solution, this is considered to be an element of experimental design which is well within the purview of one of skill in the art and a mere optimization step in the absence of evidence to the contrary. See MPEP 2144.05 II.A.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions and/or additions in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

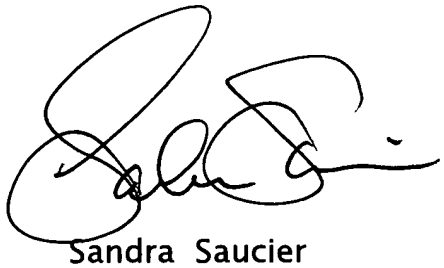
Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. a copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone

number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651
June 28, 2005